

**CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY  
OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT**

**SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT OF 1986  
(PROPOSITION 65)**

**NOTICE TO INTERESTED PARTIES**

**WORKSHOP ON POTENTIAL REGULATORY ACTION  
EXEMPTING FROM THE PROPOSITION 65 WARNING REQUIREMENTS,  
EXPOSURES FROM CHEMICALS THAT FORM FROM NATURAL  
CONSTITUENTS IN FOOD DURING COOKING OR HEAT PROCESSING**

**April 8, 2005**

On May 9, 2005 the Office of Environmental Health Hazard Assessment (OEHHA) will conduct a public workshop to explore a potential regulatory action exempting from the Safe Drinking Water and Toxic Enforcement Act of 1986<sup>1</sup> (hereafter Proposition 65 or the Act) warning requirements, exposures to listed chemicals that form from natural constituents in food during cooking or heat processing.

OEHHA has been designated by the Governor as the lead agency for Proposition 65<sup>2</sup>, and as the lead agency has the authority to adopt and modify regulations “as necessary to conform with and implement” the Act “and to further its purposes.” OEHHA has adopted and applied regulations on exposures to listed chemicals in foods (e.g. Title 22, Cal. Code of Regs, Sections 12713, 12501 and 12703(b)<sup>3</sup>) and a background on those regulations is included with this notice.

In 2002 Swedish scientists reported that acrylamide, a chemical listed under Proposition 65, was formed in food from natural constituents as a result of cooking or heat processing. This chemical is found in many foods that are commonly consumed in California and it may be impossible to reduce to levels that would not require a warning. Concerns have been expressed that providing Proposition 65 warnings on many common food products may cause some consumers to avoid foods that may be necessary for a balanced diet. Additionally, the issue of over-warning or “warning fatigue” has been raised as well as the potential for conflict with federal food labeling laws. Therefore, OEHHA is considering the adoption of a limited exception to the warning requirements of the Act for exposures to chemicals that are formed from natural constituents as a result of cooking or heat processing.

**PROPOSED ACTION**

OEHHA is considering the possibility of a rulemaking that would provide a limited exemption from the warning requirements of the Act, under specified circumstances, for

---

<sup>1</sup> Health and Safety Code Section 25249.5 et seq.

<sup>2</sup> Health and Safety Code, Section 25249.12

<sup>3</sup> All further references are to Title 22 of the California Code of Regulations, unless otherwise indicated

exposures to listed chemicals that form in a food solely as a result of naturally occurring constituents in the food being cooked or heat processed. Such an exemption would be adopted as a separate regulation. Proposed regulatory language, for purposes of discussion only, is set out below. This language may change significantly in any subsequent rulemaking action.

*New Section \_\_\_\_\_, Chemicals Formed From Natural Constituents in Foods*

‘For purposes of Health and Safety section 25249.6, an exposure does not occur if the person otherwise responsible can show that the chemical in question formed solely from constituents naturally present in food and as a result of the food being cooked or heat processed, and that the concentration of the chemical in question has been reduced to the lowest level currently feasible using good cooking and manufacturing processes.’

OEHHA is soliciting input from the public concerning the positive and negative issues to be considered in such a rulemaking process. The public is invited to attend a public workshop to be held on Monday, May 9, 2005 at 10:00 a.m. in the Coastal Hearing Room at the California Environmental Protection Agency, 1001 I Street, Sacramento, California. The workshop will begin at 10:00 a.m. and will end when all business is conducted or 5:00 p.m. In the alternative, any interested person may submit comments to:

Ms. Cynthia Oshita  
Office of Environmental Health Hazard Assessment  
Street address: 1001 I Street  
Sacramento, California 95814  
Mailing address: P.O. Box 4010  
Sacramento, California 95812-4010  
Fax No.: (916) 323-8803  
Telephone: (916) 445-6900

**Comments may also be delivered in person or by courier to the above address. It is requested, but not required, that written comments and supporting documentation be transmitted via email addressed to: [coshita@oehha.ca.gov](mailto:coshita@oehha.ca.gov). In order to be considered in the initial drafting process, comments must be postmarked (if sent by mail) or received at OEHHA (if hand-delivered, sent by FAX, or transmitted electronically) by 5:00 p.m. on Monday, May 9, 2005. In the event OEHHA proceeds with a rulemaking proposal, additional opportunities for public input will occur.**

## REGULATORY BACKGROUND FOR EXPOSURES TO PROPOSITION 65 CHEMICALS IN FOOD

The following summarizes the history of regulatory efforts that OEHHA and its predecessor agency has taken to address exposures to listed chemicals in foods. This information is being provided in order to help ensure that the discussion at the workshop is productive and that the participants are well informed about the history and context for the present proposal. Copies of all relevant documents referred to in this discussion are attached and are also available on the OEHHA website at [www.oehha.ca.gov](http://www.oehha.ca.gov).

Since the adoption of the Safe Drinking Water and Toxic Enforcement Act of 1986, various stakeholders have requested that OEHHA or its predecessor, the Health and Welfare Agency, exempt certain types of exposures to listed chemicals, particularly those related to foods and drugs from the warning requirements of the Act. Following is a discussion of the various regulatory actions that have been taken in regard to chemical exposures from foods.

### *Former Section 12713<sup>4</sup> – Exposures to Food, Drugs, Cosmetics and Medical Devices*

An emergency regulation adopted in 1988, Section 12713, that had been interpreted as providing an exemption from the warning requirements of the Act for all exposures from all food, drugs and cosmetics that complied with federal law, was repealed in 1993, following a trial court finding that the regulation was null and void.<sup>5</sup> According to the Final Statement of Reasons, Section 12713 was repealed based on findings by the agency that the Act expressly applies to foods, food products, drugs, cosmetics and medical devices, and that other regulatory provisions superceded the regulation.<sup>6</sup> Since that time, OEHHA has taken the position that such a blanket exemption from the warning requirements of the Act is beyond the scope of its authority. However, OEHHA's predecessor, the Health and Welfare Agency did develop regulations that provide more narrow exemptions for certain types of exposures to listed chemicals, or that allow for higher exposures in certain situations (Section 12501 and Section 12703(b) respectively).

### *Section 12501 – Naturally Occurring Chemicals*

When adopting Section 12501 in 1989, OEHHA stated that the regulation, which exempts exposures to 'naturally occurring' chemicals from the warning requirements of the Act under certain circumstances, could not be expanded to include cooking because cooking is a 'known human activity' that can result in the addition of listed chemicals to food.<sup>7</sup> For example, the Final Statement of Reasons for Section 12501 states that:

'Several comments requested that 'human activity' exclude 'customary methods of food processing' because they are such an integral part of the food supply system that they are not discretionary activities. Since chemicals in food, which are caused by cooking, fermentation, or any other processing, are added to the food by human

---

<sup>4</sup> All references are to Title 22 of the California Code of Regulations, unless otherwise indicated

<sup>5</sup> Settlement Agreement, *AFL-CIO et al. v Deukmejian* (Sacramento Superior Court case no. 502541)

<sup>6</sup> Final Statement of Reasons, repeal of Section 12713

<sup>7</sup> Final Statement of Reasons, Section 12501 and Letter dated February 11, 2003 to Michelle Corash, Morrison & Foerster

agency, they are the result of known human activity, and thus cannot be considered naturally occurring.’<sup>8</sup>

Section 12501 was patterned on federal food adulteration laws<sup>9</sup> that regulate the presence of deleterious substances in food. These federal laws apply to chemicals that are “added” to foods as a result of human actions. The term “added” has been interpreted by federal courts to mean that a substance is added to a food if it is artificially introduced, or attributable in some degree to the acts of man.<sup>10</sup>

Section 12501 provides an exemption from the warning requirements of the Act for exposures to listed chemicals in foods that are “naturally occurring.” The term “naturally occurring” is defined in the regulation as follows:

“A chemical is ‘naturally occurring’ if it is a natural constituent of a food, or if it is present in the food solely as a result of absorption or accumulation of the chemical which is naturally present in the environment in which the food is raised, grown, or obtained; for example minerals present in the soil solely as a result of natural geologic processes, or toxins produced by the natural growth of fungi.”

The regulation goes on to require that even where a chemical can be considered “naturally occurring,” the level of the chemical in the food must be reduced to the lowest level currently feasible through the use of good agricultural or good manufacturing processes.

The regulation does not define the term “human activity” but states that it does not include sowing, planting, irrigation, or plowing or other mechanical preparation of soil for agricultural purposes; but does include the addition of chemicals to irrigation water supplied to soil or crops. According to the Final Statement of Reasons, these activities were exempted because they were not likely to result in the addition of harmful chemicals to the food.

Following the adoption of Section 12501, the regulation withstood a legal challenge in *Nicolle-Wagner v Deukmejian*.<sup>11</sup> The plaintiff in that case argued that the regulatory action was invalid because Proposition 65 did not allow for any differentiation between chemicals that are added by human activity or are merely present naturally in the food, and the implementing agency had no authority to adopt a regulation that was in conflict with the purpose of the Act. The court in the *Nicolle-Wagner* case determined that the implementing agency had the limited authority to adopt regulations that are consistent, not in conflict with and reasonably necessary to effectuate the purpose of the statute and that this particular regulation was not in conflict with the purposes of the Act. The court focused on language in the Act that provides that “no person in the course of doing business shall knowingly and intentionally expose any individual” and interpreted the phrase to require some level of human activity that results in the chemical being added to the environment as required under the Act.

---

<sup>8</sup>Final Statement of Reasons, Title 22, Cal. Code of Regs. Section 12501 at page 9

<sup>9</sup> 21 USC Section 342(a) and 21 CFR Section 109.3

<sup>10</sup> *United States v Anderson Seafoods, Inc* (1980, 5<sup>th</sup> Circuit) 622 F.2d. 157 at page 160.

<sup>11</sup> *Bryan Nicolle-Wagner v George Deukmejian* (1991) 230 Cal. App.

*Section 12703(b) – Alternative Risk Levels*

The other regulation that can be used to address exposures to listed chemicals in foods is Section 12703(b) which allows for the establishment of an “alternative risk level” that may be higher than the standard where “sound considerations of public health” support such a level. An example relevant to foods is given in Section 12703(b)(1): “where chemicals in food are produced by cooking necessary to render the food palatable or to avoid microbiological contamination.” This provision does not provide an exemption from the warning requirements of the Act, but may be applied in such a way as to exempt exposures at or below the alternative risk level from the warning requirements of the Act based upon sound considerations of public health.

Many other Proposition 65 regulations can apply to exposures to chemicals that may be present in foods including the “safe harbor” warning provisions of Section 12601, No Significant Risk Levels in Section 12701, Levels of Exposure in Sections 12721 and 12821, No Observable Effects Levels in Section 12801, and the like. These regulations do not directly relate to the context for the proposed regulatory action, so they are not discussed here.